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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,720	02/15/2001	Klaus Abraham-Fuchs	P00,1222	2613

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EXAMINER	
MAHATAN, CHANNING	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/784,720	ABRAHAM-FUCHS ET AL.	
	Examiner	Art Unit	
	Channing S. Mahatan	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-8 and 10-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-8 and 10-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 February 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' submission of the listing of claims to place the claims in compliance according to proper status identifiers in the '*RESPONSE*', filed 27 April, is acknowledged.

Applicants' arguments, filed 13 August 2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 2-8 and 10-18. Claims 1 and 9 have been cancelled.

EXAMINER COMMENT

It appears Applicants have neglected to directly address the issues pertaining to the claims rejected under 35 U.S.C. § 112 2nd Paragraph, wherein absent in Applicants' response are traversal arguments specifically regarding this rejection or indication of claims rejected under this statute. Note the second paragraph of the '*REMARKS*' section does not indicate pending rejections under 35 U.S.C. § 112 2nd Paragraph. The Examiner has attempted to decipher from Applicants arguments issues pertinent to the rejections under 35 U.S.C. § 112 2nd Paragraph from issues pertinent to rejections under 35 U.S.C. § 112 1st Paragraph.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

NEW MATTER

The rejection of claims 2-8 and 10-18 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement are maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants appear to point to: 1) the paragraph bridging pages 2 and 3 for support of the language "...each sensitive for multiple biomolecular markers"; and 2) the paragraph bridging pages 7 and 8 for support of the language "follow-up diagnostic data as a training data set". However, this no such support can be found.

Claims 7, 17, 18, and all claim dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph. For clarification, the term "sensitive" and not "sensitivity" is specifically recited in the claims. The introduction of the language "...each sensitive for multiple biomolecular markers..." (claims 7 and 17); and "follow-up diagnostic data as a training data set" (claims 17 and 18) is considered new matter, since there does not appear to be any disclosure or contemplation for new claims 17 and 18 and the amendment to claims 7. The paragraph bridging pages 2 and 3, which appears to be cited by Applicants' for the support of "sensitive", states:

> "The above object is achieved in accordance with the principles of the present invention in a network and a method for collecting data and diagnostic testing wherein a biochip with a multi-marker diagnostic test is employed. The biochip has a marker array, which can include "hidden" markers in addition to approved markers, the "hidden" markers not being used for making a current diagnostic decision with the approved markers. For each investigated patient, and electronic patient record (EPR) is produced, wherein the measurement results from the biochip are stored, including the "hidden" markers, if present. The final target diagnostic decision obtained

> from the measurement results is also stored in the EPR. These entries into the patient's EPR can be stored in the same data file on the same storage device as the measurement results from the biochip, or can be organized as separate segments of a physically distributed EPR, the different segments being connected by means of a digital data network. A central data bank is in communication with storage sites for the individual EPRs of the patients enrolled in a clinical study, and the central data bank collects the data from all of the individual EPRs. Follow-up data are entered into the EPRs, which indicates whether the diagnosis based on the biochip measurement was, in fact, correct. The central data bank is in communication with a processor which employs an algorithm to test new hypotheses on the data stored in, or accessible by, the central data bank, so as to identify optimized evaluation rules for new or existing multi-marker tests. The evaluation rules are presented at a user interface, and may be documented together with the underlying EPR clinical study data for an approval procedure. The data link between the central data bank, which can be a central server, and the individual storage sites for the EPRs (or sites for EPR data entry) can be conducted via the Internet or e-mail."

The above paragraph does not recite "sensitive" nor provides conceptual language to such effect (i.e. criteria/threshold value indicative of being "sensitive"; Refer to below 35 U.S.C. § 112 2nd Paragraph Rejection). The paragraph bridging pages 7 and 8, which appears to be cited by Applicants' for support of "follow-up diagnostic data as a training data set", states:

> "The results of the diagnostic test conducted using the "cervical cancer biochip" are entered into and stored in the EPR of the patient, which is accessible at the point of care site via a data entry station. Since no medical diagnostic test can be unequivocally stated to have a 100% accuracy, there will always be the possibility of a false positive result or a false negative result. In false positive cases, the patient (as a result of the false positive diagnosis) will be referred to a clinic for further evaluation, such as for conducting a biopsy. The biopsy analysis will show that there is, in fact, no cancer present, and this will also be indicated in the patient's EPR. In false negative cases, i.e., where an existing cancer is not diagnosed by the biochip, there will come a time within weeks or months wherein the patient will, in fact, be diagnosed to have cervical cancer, and such a diagnostic entry will be made in the patient's EPR. Thus, over time, every EPR will contain a data entry such as "biochip measurement result" and a follow-up entry (in some form) "cervical cancel diagnosis: positive or negative". Every EPR, therefore, will contain an indication of the correctness of the biochip measurement result which, in turn, is an indication of the efficacy of the protocol used to analyze the biochip data. Automated evaluation of the EPR information is thus able to yield quantified outcome data for the specificity and sensitivity of the "cervical cancer biochip" test under consideration."

The above paragraph does not recite said language nor provides conceptual language to such an effect, wherein absent is indication that the "follow-up diagnostic data" is used as "training data set" to create "a modified expert rule with improved diagnostic value in comparison to said expert rule used to produce said diagnostic result" (refer to claims 17 and 18). None of these

concepts were found and none is apparent. Therefore, new claims 17 and 18 and the amendments to claims 2-8 and 10-16 are considered NEW MATTER.

LACK OF ENABLEMENT

The rejection of claims 2-8 and 10-18 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement are maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since it is the absence of an initial set of "expert rules" and the criteria(s)/parameter(s) that are to be utilized by the "expert system" to process the inputted information (i.e. raw biochip data) for the modification of the "expert rule(s)" to create "modified expert rules".

The following is the Examiner's request to address the enablement of the instantly claimed invention from the Office Action mailed 18 May 2004:

> "It is therefore requested Applicants provide, by example, this "easily ascertainable standard" by determining a "modified expert rule" utilizing any of the expert systems in the prior art with the raw biochip data from Mendoza et al. Given Applicants assertion of such an "easily ascertainable standard": What is the initial set of "expert rules" of Mendoza et al.? How are these "expert rules" modified to derive a "modified expert rule with improved diagnostic value in comparison to said expert rule used to produce said diagnostic result"?" (pages 5-6, beginning on line 16)

Applicants have responded in the Amendment filed 13 August 2004 by stating the following:

> "...Applicants have never contended that Mendoza et al. describes, or is intended to describe, an expert system or a neural network." (page 9, lines 19-22)

> "...It cannot be stressed heavily enough that the details of the expert rules that are set forth in the claims of the present application have never been regarded by the Applicants as a part of their invention. The Applicants consider the distinguishing features of their invention with respect to the prior art to be in the data gathering and compilation and the ability to perform networked transmission of data to an expert system." (page 8, lines 14-19)

Applicants' then proceed to discuss Anderson et al. (previously applied under 35 U.S.C. § 103 with Mendoza et al. in the Office Action mailed 08 September 2003) and the manner it is

"directed to improving the output of a neural network by improving the quality of the data that are entered into the neural network." It should be noted Anderson et al. taken in view of Mendoza et al. was dropped based on Applicants argument that Anderson et al.:

> "provides no teaching or information whatsoever regarding...how the collected data are employed to generate a modified expert rule (or even if the collected data are used for that purpose)." (Amendment, file 08 December 2003, page 10, lines 10-13).

The question regarding the enablement of the instantly claimed invention, in view of the specification and teaching in the prior art, has been brought about based on Applicants previous arguments (Amendment, filed 08 December 2003) and maintained arguments that the derivation of "expert rules" and "modified expert rules" therein, is an "easily ascertainable standard". Applicants' assertion appears to set forth the establishment of the knowledge possessed by one of ordinary skill in the art to make and/or use the instantly claimed invention, which is being questioned by the Examiner. If such standard is "easily ascertainable" then Applicants should have no difficulty in deriving the requested "expert rules" and "modified expert rules" from raw biochip data as taught in, for example, Mendoza et al. Additionally, Applicants have submitted:

> "...the Examiner is hugely over-complicating Applicants' claimed subject matter, by looking for factors that Applicants never intended to include as part of their invention, as well as by underestimating the level of knowledge possessed by those of ordinary skill in the field regarding the use of expert systems/neural networks." (page 11, lines 4-8)

which is not found convincing for the reasons above and is further questioned as follows: 1) If Applicants' never intended these factors (criteria/parameters) that are embraced by the claim language to be included as part of their invention it is then unclear why Applicants' have included such language (the absence of these factors it becomes unclear of the manner in which one of skill in the art can assess it's use and apply it to the instantly claimed invention; and 2) based on Applicants' argument that the Examiner is "underestimating the level of knowledge

possessed by those of ordinary skill in the field" then it should be relatively easy for Applicants (i.e. skilled in the art) to derive "expert rules" and "modified expert rules" from Mendoza et al., as previously requested and maintained to be requested by the Examiner, since it is beyond the level of understanding of the Examiner to derive these "expert rules" and "modified expert rules" from said reference.

Therefore, in the absence of an initial set of "expert rules" and the criteria(s)/parameter(s) for modification one of skill in the art would be required to make independent decisions, judgements, tests, and validations to: 1) derive the initial set of expert rules; 2) ascertain the rules by which the "expert system" processes the information to generate modified diagnostic expert rules that have an improved diagnostic value when compared to the initial set of "expert rules"; and 3) testing and validating the "expert rule" derivation and the process for creation of a modified diagnostic expert rule", which is not considered routine. Thus, the specification fails to provide one of skill in the art proper guidance, direction, or examples to make and use the claimed method and system.

Claims Rejected 35 U.S.C. § 112 2nd Paragraph

The rejection of claims 2-8 and 10-18 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are maintained for reasons of record.

VAGUE AND INDEFINITE

Claims 7, 17, and all claims dependent therefrom recite the limitation "said biochips are sensitive for more biomolecular markers than said predetermined number of biomolecular

markers..."/"a plurality of disposable biochips, each sensitive for multiple biomolecular markers..." which is vague and indefinite. Applicants argue:

> "...the term "sensitivity" in the claims...is being used in accordance with its normal dictionary definition and the definition which scientists understand with respect to any type of detector device..." (page 7, lines 13-15 of the 'Remarks')

However, this argument is found unpersuasive. Again, the term "sensitive" and not "sensitivity" is specifically recited in the claims. Merriam-Webster's Collegiate Dictionary (Tenth Edition, 1999, page 1066) defines:

> "sensitive" as "...readily affected or changed by various agents (as light or mechanical shock)";

and

> "sensitivity" as "...the quality or state of being sensitive"

Applicants' statement, in view of the its normal dictionary definition, appear to support the implied criteria/threshold value that the Examiner associates with the term "sensitive" or "sensitivity" (i.e. quality) indicative of said biochips to be "sensitive" for multiple biomolecular markers. Applicants' further state:

> "...wherein the term is being used to mean no more than the fact that the biochip is able to detect, or react to, certain types of biomarkers." (page 7, lines 17-19 of the 'Remarks')

which is interpreted to mean that if the biochip is able to detect or react to certain types of biomarkers then is considered "sensitive", conversely, if it is "not sensitive" then the biochip is unable to detect and react to certain types of biomarker. What then are the criteria(s)/threshold value(s) that establishes a biochip to be "sensitive" for certain types of biomarkers as opposed being "not sensitive" for certain other types of biomarkers? Thus, Applicants' can resolve this issue by particularly pointing out the selection criteria/threshold value that establishes a biochip to be "sensitive" and the criteria/threshold that establishes a biochip to be "sensitive for more

biomolecular markers than said predetermined number of biomolecular markers". Clarification of the metes and bounds, via clearer claim language is requested.

Claim 17 and all claims dependent therefrom recites the limitation "...creating a modified expert rule with improved diagnostic value in comparison to said expert rule used to produce said diagnostic result..." which is vague and indefinite. The above limitation implies a set of criteria that establishes the "modified expert rule" is an improvement in diagnostic value over that of the said expert rule used to produce said diagnostic result. Applicants' did not address this rejection in the arguments, filed 13 August 2004. Applicants' can resolve this issue by particularly pointing out the criteria that establishes the modified expert rule is indeed an improvement over that of said expert rule used to produce said diagnostic result. Clarification of the metes and bounds, via clearer claim language is requested.

ACTION IS FINAL

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The Fax Center number is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify Applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables Applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Examiner Initials: CSM

Date: July 1, 2005

Ardin H. Marschel 7/3/05
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER